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HEMOSTATIC COMPOSITIONS

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This invention relates to new and improved hemostatic compositions and specifically relates to such compositions that are absorbable in body fluids by physiologic processes.

Various substances and compositions have been employed by members of the medical profession to control bleeding of soft tissues and cut bone surfaces. Natural clotting agents such as striated muscle have been used, particularly in neurosurgery and in drill holes in bone. Certain plasma fractions have been used, and fibrin from whipped blood has been so prepared that it could be immediately plastered on bleeding surfaces. Human fibrin foam has been used as a carrier of thrombin, and the fibrin foam has been used in the form of a dry, porous, brittle, cream-colored textile. Another plasma protein, thrombin, in a highly potent, purified, water-soluble form has been used as a hemostatic spray as well as in conjunction with human fibrin foam, but thrombin is unstable in aqueous solution and cannot be heat sterilized in an autoclave without destroying its activity as a hemostatic substance. Fibrinogen in conjunction with thrombin has also been found useful in the formation of an adhesive layer to seal together cut surfaces of soft tissues, notably a skin graft on a prepared bed. More recently an absorbable substance in the form of a sponge has been used and is prepared from a specially prepared gelatin solution which is further processed and sterilized. The gelatin sponge when dry is a light, off-white, reasonably tough, porous substance that may be readily cut by a sharp instrument into any desired shape or size. This absorbable gelatin sponge is normally used in conjunction with a thrombin solution. The gelatin sponge mixed with the thrombin solution is used by applying it to a bleeding area where it quickly imbibes blood which clots as it comes in contact with thrombin. Physiological absorption of the sponge takes place in from 15 to 20 days.

Another recent absorbable substance which has found acceptance by the medical profession as a hemostatic agent is oxidized cellulose. It was found that oxidized cellulose in the form of cotton, paper, gauze, or a non-woven mass had hemostatic properties, and its use as a hemostatic agent has been widely studied in a variety of animal and human tissues. The material was demonstrated to be non-irritating and to disappear in the tissue leaving a minimum of scar.

The control of osseous hemorrhage has presented a serious problem to the medical profession because the hemostatic agents found effective for the control of soft tissue hemorrhages

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have not been effective for the control of bleeding from cut bone surfaces. One class of materials used for the control of this latter type of hemorrhage is called bone wax. Bone waxes in common use today are prepared from refined waxes of bees which have been admixed with other non-absorbable and water-insoluble hydrocarbons or vegetable oils. Bone wax has been used for the purpose of controlling hemorrhages from the cut surfaces of bones, such as those of the skull, by forcibly smearing the wax over the cut surface so that the material acts mechanically to occlude and seal the open ends of bleeding osseous vessels and sinuses. Such compositions have no specific hemostatic effect per se and quite often result in delayed healing because of their non-absorbable properties. Non-absorbable bone waxes, since they are left in the wound as a foreign body, frequently constitute a troublesome barrier to subsequent osseous union. Another disadvantage of non-absorbable bone wax is the danger of particles of the wax falling off the bone edge and lodging in the surrounding tissue where they provide a foreign body response which retards healing and may result in an inflammatory tissue response.

It is an object of this invention to prepare a hemostatic composition which is completely absorbable by body tissues.

It is another object of this invention to prepare a hemostatic composition which quickly controls hemorrhages from the cut surfaces of soft tissues and more particularly bones.

It is another and further object of this invention to prepare an absorbable hemostatic composition which possesses a specific hemostatic effect and is at the same time absorbable by physiologic processes.

It is still another and further object of this invention to prepare an absorbable hemostatic composition which is readily sterilizable by ordinary autoclaving procedures.

Other objects will be apparent from the following description and examples.

In accordance with the present invention it has been found that hemostatic compositions which have a specific hemostatic effect and in which the range of consistency varies from a highly viscous liquid to that of a soft wax and from a soft wax to that of a semi-solid or solid may be prepared which include as ingredients a water-soluble innocuous base and a hemostatic agent. The base may be a single substance or a mixture of two or more water-soluble innocuous substances, and the hemostatic agent is prefer-